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Robert Karlsson

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04/06/2009

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EXAMINER

GABEL, GAILENE

ART UNIT

PAPER NUMBER

1641

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ADVISORY ACTION

Amendment Entry

1. Applicant's amendment and response filed March 23, 2009 is acknowledged and has been entered. Claim 1 has been amended. Claims 3, 4, and 14-19 have been cancelled. Accordingly, claims 1, 2, 6, 7, and 10-19 are pending. Claims 1, 2, 6, 7, and 10-13 are under examination.

Withdrawn Rejections/Objections

2. All rejections or objections not reiterated herein, have been withdrawn.
3. The rejections of claims 3 and 4 are now moot in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 2, 6, 7, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wahlstrom et al. (WO 96/38729) in view of Malmqvist et al. (US Patent 5,492,840) and in further view of Willmann et al. (US Patent 6,495,333) for reasons of record.

Response to Arguments

5. Applicant's arguments filed March 23, 2009 have been fully considered but they are not persuasive.

A) Applicant argues that there are feature that distinguish the claimed invention from the Wahlstrom et al. reference; first, that the Wahstrom method describes a competitive assay whereupon the method requires that antibody is separated from cells prior to analysis whereas that the separation step is not required in the claimed invention. Applicant further states that at linear flow rates, cell and cell fragments do not readily migrate down to the sensor surface and therefore in Applicant's method, cell or cell fragments do not need to be separated from the cell sample fluid before subjecting the ligands to binding of the solid support.

In response, claim 1 does not appear to exclude the separation step taught by Wahlstrom, especially that Applicant's disclosure actually teaches optionally separating the cells. The transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Additionally, nowhere in the claim or Applicant's disclosure appears to recite or define that Applicant's method is performed at high linear flow rates that disallow cells and cell fragments from readily migrating down to the sensor surface; hence, not necessitating the unrecited separation step. Accordingly, the combination of Wahlstrom with Malmqvist and Willmann appears to suggest the claimed invention.

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6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

April 1, 2009